

REMARKS

This is a full and timely response to the outstanding nonfinal Office Action mailed April 10, 2002. Reconsideration and allowance of the application and presently pending claims, as amended, are respectfully requested.

1. Present Status of Patent Application

Upon entry of the amendments in this response, claims 8, 10-14, 16-18, and 23-33 remain pending in the present application. More specifically, claims 8, 10-14 and 16-18 are directly amended; claims 9 and 15 are canceled without prejudice, waiver, or disclaimer; and claims 24-33 are added. These amendments and additions are specifically described hereinafter. It is believed that the foregoing amendments and additions add no new matter to the present application.

2. Miscellaneous Issues

Claims 9 and 15 are canceled without prejudice, waiver, or disclaimer. Applicants take this action merely to reduce the number of disputed issues and to facilitate early allowance and issuance of other claims in the present application. Applicants reserve the right to pursue the subject matter of these canceled claims in a continuing application, if Applicants so choose, and do not intend to dedicate any of the canceled subject matter to the public.

Applicants note that the drawings were objected to for the reasons on form PTO 948. Unfortunately, form PTO 948 did not accompany the Office Action. Applicants wish to note for the record that the cover sheet, or Office Action Summary, did not have Attachment box 2 checked (Notice of Draftsperson's Patent Drawing Review (PTO 948)). Applicants are happy to comply once the form has been received.

The Office Action alleges that referenced German patent 0348348 (the '348 reference) in the Information Disclosure Statement failed to comply with provisions of 37 C.F.R. 1.97 and 1.98. Applicants respectfully traverse this rejection. The '348 reference was cited in the PCT International Search Report, which was submitted with the originally-filed patent application. According to 37 C.F.R. 1.98, an Office Action from a foreign patent office indicating the relevance of the cited art is all that is necessary. This requirement was fulfilled when the present patent application was filed. According to Rule 1.98, an English translation

of a foreign patent is only required when the translation is within the control, custody, or readily available to the individual designated in 37 C.F.R. 1.56(c). A translation of the '348 reference is not within the control, custody, or readily available to any such individual. Applicants believe that the prior-submitted International Search Report suffices the requirements of 37 C.F.R. 1.98, and respectfully requests that the objection be withdrawn and the present patent application be considered in view of said reference.

3. Response To Objections/Rejections

Response To Objections To Specification

The Examiner objected to the specification, alleging that, as the application contained sequence disclosures for nucleotide and/or amino acid sequences, the SEQ. ID. NO: must accompany all sequences and all references to sequences within the specification and claims. Accordingly, Applicants have amended the specification to insert the appropriate SEQ. ID. NO: at the appropriate point in the specification. Thus, Applicant respectfully requests that this objection be withdrawn.

The application was further objected to as it allegedly did not contain an Abstract of the disclosure and it was requested that an Abstract on a separate sheet be submitted. Applicants wish to note that an Abstract was submitted with the originally-filed patent application on the cover page of the PCT published International Application. Applicants have, however, resubmitted the Abstract herewith on a separate sheet as requested.

Claim 8 was objected to as allegedly being in improper form of a multiple dependent claim that does not refer to other claims in the alternative only. Accordingly, Applicants have amended claim 8 to remove its multiple dependency by inserting portions of original claims 1 and 9 into an amended claim 8. Thus, Applicant believes that it has overcome this objection, as well as the objection to claim 8 for being dependent upon a non-elected claim.

Claims 15 and 17 were objected to for informalities. Claim 15 has been cancelled, thus rendering all objections of that claim moot. Additionally, claim 17 has been amended to obviate the rejection of an improper article before "biologically" in line 1.

Additionally, claim 15 was objected to for being of improper dependent form for failing to further limit the subject matter of the previous claim. Without addressing the veracity of that assertion, Applicant has cancelled claim 15 without prejudice, waiver or disclaimer. The Office may wish to note that newly added claim 23 incorporates the subject matter of both

original claims 14 and 15.

Response To Claim Rejections Under 35 U.S.C. Section 112, First Paragraph

Claims 8-15 and 17-18 have been rejected under 35 U.S.C. Section 112, first paragraph, as allegedly containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Claim 15 has been cancelled without prejudice, waiver or disclaimer and thus rejection of this claim has been rendered moot.

Applicants respectfully traverse the rejection of claims 8-14 and 17-18. One skilled in the art, on the basis of the specification and general knowledge, and without any undue experimentation, should be able to isolate further DNA molecules that encode cysteine protease inhibitors with type I repeated thyroglobulin domains, where the proteins control insects. This is within the ordinary skill of one in the art, and the present invention as claimed in claims 8-14, and 17-18 clearly claim DNA molecules that encode cysteine protease inhibitors with type I repeated thyroglobulin domains.

In addition to the DNA isolation methods described in the specification, U.S. Patent No. 6,312,913 to *Wang et al.* discloses methods for determining nucleic acid sequences based on known sequences adjacent to unknown sequences, and reagents for using such methods. Applicants believe that this sufficiently demonstrates their conception of the claimed invention by defining it by its physical and chemical properties and characteristics that are sufficient to distinguish it from other materials with similar biological properties. Thus, Applicants respectfully request that the rejection of claims 8-14 and 17-18 be withdrawn.

Claim 16 has also been rejected under 35 U.S.C. Section 112, first paragraph as allegedly containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains to make and/or use the invention. Applicants respectfully traverse. The plasmid CAB1 referred to in claim 16 is not essential to the claimed invention. Indeed, the plasmid used in the examples in the specification is a common plasmid which is known to one skilled in the art. If desired, Applicants are happy to provide references disclosing the starting plasmid. It should be noted that such references are readily available to one skilled in the art. Thus, Applicants respectfully request that the rejection of claim 16 be withdrawn.

Claims 8-15 and 17-18 have also been rejected under 35 U.S.C. Section 121, first paragraph, as allegedly not providing enablement for a method of protecting a plant against insect or nematode infestation. Applicants believe that the description of the claimed process in the specification, as well as in the working examples, would indeed enable one skilled in the art, with general knowledge and without any undue experimentation to isolate the DNA molecules as claimed and use them to protect a plant against insect or nematode infestation. Thus, Applicants respectfully request that the rejection of claims 8-14 and 17-18 be withdrawn.

Response To Claim Rejections Under 35 U.S.C. Section 112, Second Paragraph

Claims 8-18 have been rejected under 35 U.S.C. Section 112, second paragraph, as allegedly being indefinite. As noted above, claims 9 and 15 have been cancelled without prejudice, waiver, or disclaimer, thus rendering moot the rejection of these claims.

In particular, claims 8-12 were alleged as being indefinite because they lacked agreement between the preamble of the methods and the positive method steps. Applicants have amended claim 8 to list the last step as regenerating resistant whole plants from the cells or tissue, which should obviate this rejection. Additionally, because claim 9 has been inserted into claim 8, Applicants believe they have overcome the rejection of claim 9 for not being clear as to where steps (a) – (c) occur in relation to the “inserting” step of claim 8.

Applicants believe they have also addressed the informality issues with claims 10-18 based on the afore-mentioned amendments to these claims. Applicant wishes to clarify that the foregoing amendment are cosmetic in nature and are not made as a condition for obtaining a patent. Applicant further submits that these amendments are non-narrowing and, pursuant to *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 122 S. Ct. 1831 (2002), no prosecution history estoppel arises from these amendments. Thus, Applicants respectfully request the rejection of claims 8-18 be withdrawn.

Response To Claim Rejections Under 35 U.S.C. Section 102

Claims 15 and 17 have been rejected under 35 U.S.C. Section 102(b) as allegedly being anticipated by *Walsh, et al.* (WO 9221753). For a proper rejection of a claim under 35 U.S.C. Section 102(b), the cited reference must disclose all elements/features/steps of the claim., See, e.g., *E.I. du Pont de Nemours & Co. v. Phillips Petroleum Co.*, 849 F.2d 1430, 7 USPQ2d

1129 (Fed. Circ. 1988). The Office may wish to note that the subject matter of claim 15 has been incorporated to newly added claim 24. Claims 17 and 24 are allowable for at least the reason that *Walsh, et al.* do not disclose, teach, or suggest a cysteine protease inhibitor of the thyroglobulin family. *Walsh, et al.* instead disclose a cysteine protease inhibitor which is a member of the phytocystatin family, and is *not* a functional derivative of SEQ. ID. NO.: 2. Thus, *Walsh et al.* do not anticipate or render obvious claims 17 or 24, and Applicants respectfully request that the rejection be withdrawn.

4. New Claims

Claim 24-33 have been newly added to further define and/or clarify the scope of the invention. Newly added claim 24 incorporates the features of both original claims 14 and 15, as well as listing the specific SEQ ID NO, or functional derivatives thereof, for the protein expressed in plant cells. As noted above, it is not anticipated or obvious in view of the cited prior art, and is believed to be enabled by the specification.

Further, new claims 25-33 are also believed to be allowable over the cited prior art, as well as in view of 35 U.S.C. 112, first and second paragraphs.

5. Prior Art Made of Record

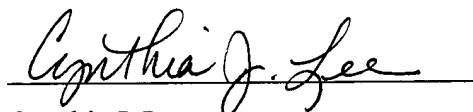
The prior art made of record has been considered, but is not believed to affect the patentability of the presently pending claims.

CONCLUSION

Applicants respectfully submit that all claims are now in proper condition for allowance, and respectfully request that the Examiner pass this case to issuance. If, in the opinion of the Examiner, a telephone conference would expedite the examination of this matter, the Examiner is invited to call the undersigned attorney at (770) 933-9500.

No fee is believed to be due in connection with this response. If, however, any fee is deemed to be payable, you are hereby authorized to charge any such fee to Deposit Account No. 20-0778.

Respectfully submitted,

A handwritten signature in cursive script, reading "Cynthia J. Lee", written over a horizontal line.

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ANNOTATED VERSION OF MODIFIED CLAIMS TO SHOW CHANGES MADE

The following is a marked up version of the amended claims. Amend the following claims by adding the language that is underlined (“ ”) and by deleting the language that is enclosed within brackets (“[]”):

8. (Once Amended) [The method of any claims 1 to 7,] A method of protecting a plant or a part of said plant against insect or nematode infestation by one or more insects or nematodes having digestive cysteine proteases, comprising the steps of:

- (a) culturing cells or tissue from the plant;
- (b) inserting into the genome of the [plant] cells or tissue a sequence coding for a [protein] cysteine protease inhibitor selected from the group of proteins containing at least one type repeated thyroglobulin domain, with a promoter sequence active in the plant to cause expression of said protein at levels which provide an insect or nematode controlling amount of said protein; and
- (c) regenerating resistant whole plants from the cells or tissue.

10. (Once Amended) The method according to claim [9] 8, which comprises the further step of (d) sexually or clonally reproducing the whole [plant] plants in such a manner that at least one copy of the sequence coding for the protein containing at least one type I repeated thyroglobulin domain with a promoter sequence active in the plant is present in the cells of [progeny of the reproduction], the reproduced plants.

11. (Once Amended) The method according to claim 10, further comprising the steps of:

- (a) [selecting] providing a fertile [insect or nematode resistant] plant prepared by the method of claim 10, which plant is either insect or nematode resistant;
- (b) sexually crossing the insect or nematode resistant plant with a plant from [the] an insect or nematode susceptible [plants from the susceptible] variety;
- (c) recovering reproductive material from the progeny of the cross; and
- (d) growing resistant plants from the reproductive material.

12. (Once Amended) The method according to claim 11, [for imparting insect or nematode resistance to a substantially homozygous population of plants of a susceptible variety] which comprises the further steps of repetitively;

(a) backcrossing the insect or nematode resistant progeny prepared by the method of claim 8 with substantially homozygous [insect or nematode susceptible] plants from [the] an insect or nematode susceptible variety; and

(b) selecting for expression of both insect or nematode resistance and [the] other characteristics of the susceptible variety among the progeny of the backcross, until the desired percentage of the characteristics of the susceptible variety are present in the progeny along with the insect or nematode resistance.

13. (Once Amended) A transgenic plant and its sexual progeny which is resistant to attack by one or more insects or nematodes having digestive cysteine proteases, said transgenic plant expressing an insect [of] or nematode controlling amount of a protein containing at least one type I repeated thyroglobulin domain.

14. (Once Amended) An [biologically functional] expression vehicle [containing] comprising a promoter effective to promote expression of a downstream coding sequence in plant cells, a DNA coding region coding for the expression in plant cells of a protein [composed of] comprising at least one type I repeated thyroglobulin domain and a termination sequence effective to terminate transcription or translation of the [genetic construction] protein product in plant cells, the [genetic construction] expression vehicle being effective to express in [the] plant cells [of the plant] insect controlling amounts of the protein [containing] comprising at least one type I repeated thyroglobulin domain.

16. (Once Amended) The [biological functional] expression vehicle of claim 14, [wherein the expression vehicle] which is pCAB1.

17. (Once Amended) A host cell transformed with [a biologically functional] the expression vehicle of [any one of claims 14 to 16] claim 14.

18. (Once Amended) The [transgenic] host cell of claim 17, wherein the DNA [sequence] coding region is controlled by a promoter effective to promote expression of a downstream coding sequence in a plant cell, the DNA [sequence] coding region coding for the expression in plant cells of a protein [composed of] comprising at least one type I repeated thyroglobulin domain and a termination sequence effective to terminate transcription or translation of [the product in plant cells] the [genetic construction] protein product in plant cells, the [genetic construction] expression vehicle being effective to express in [the cells of the plant] plant cells insect controlling amounts of the protein [composed of] comprising at least one type I repeated thyroglobulin domain to control one or more insects having digestive cysteine proteases.

ANNOTATED VERSION OF MODIFIED SPECIFICATION
TO SHOW CHANGES MADE

The following is a marked up version of the amended specification. Amend the following claims by adding the language that is underlined (“ ”) and by deleting the language that is enclosed within brackets (“[]”):

Page 43, first paragraph, lines 1-5:

manufacturer's instructions and analysed by nucleotide sequencing using T7 DNA polymerase (T7 sequencing kit, Pharmacia) and [³⁵S]dATP S (Amersham). Sequencing of selected cDNA clones resulted in the full length cDNA clone given in Figure 1. The DNA sequence of FIG. 1 corresponds to SEQ ID NO:1. The protein sequence of FIG. 1 corresponds to SEQ ID NO: 2.

Page 57, third full paragraph, lines 11-23:

The equistatin cDNA contains in the coding region several potential plant polyadenylation signals, mRNA instability motifs and a suboptimal codon usage for expression in plants. To improve the level of gene expression in plants these motifs may be removed and codons may be optimized by site specific mutagenesis without altering the primary protein sequence. Below an example of the modifications required to obtain improved gene expression in potato are given. The top strand represents the coding part of the cDNA clone, below that the suggested modifications of the cDNA sequence are given and below that the protein coding sequence is given using the one-letter code for the amino acid residues. The DNA sequence below corresponds to SEQ ID. NO: 3. The protein sequence corresponds to SEQ ID NO: 4.